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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,900

09/18/2003

William F. McKay

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12/15/2008

MEDTRONIC

Attn: Noreen Johnson - IP Legal Department

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MEMPHIS, TN 38132

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

12/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/666,900	Applicant(s) MCKAY ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19, 27, 45-47 and 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19, 27, 45-47 and 49-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the new limitation that the folded configuration has a multiplicity of “pleated” folds was not found in the written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19,27,45-47,49,50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation in claim 27, “pulling the drawstring while the implanted tissue remains essentially in place to cause folding.....” is new matter. A person of ordinary skill in the art with common sense would understand that pulling on an object would not permit that object (in this instance, the implanted tissue) to remain essentially in place unless some anchoring or

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structure secures that object (tissue) to prevent it from moving. The disclosure does not describe this.

Claims 17-19,27,45-47,49,50 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: what object keeps the tissue “essentially in place” while pulling?

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 51-53,56-58 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Gabbay (WO 02/39889). Fig. 4 shows an intervertebral disc device having a length of natural tissue **48** with a “drawstring” **50** attached at or near its first end and passes through the tissue at a plurality of sites of at least three. Because the tissue is folded, the string extends through the tissue to or near the second end to keep together the folds and draw together the ends and can be said that it extends beyond the second end such that it can be secured or knotted such that the string does not become removed from the tissue. It has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69

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USPQ 138. The string is capable of being pulled. Regarding claim 52, Gabbay discloses natural tissue, page 9, lines 8-13. With respect to claim 53, Gabbay discloses pericardium tissue, page 8, lines 17,18. Regarding claims 57,58, it can be seen that the string passes through at least ten sites on the tissue.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (WO 02/39889) in view of Sybert et al. (2002/107570). Gabbay is explained above. However, Gabbay fails to disclose the natural tissue is SIS or braided construction. Sybert et al. teach that natural tissue (small intestine submucosa) can be used to form a prosthetic device, paragraph 31. Sybert additionally teaches that braided construction can be used in tissue implants for providing greater strength, paragraphs 67-70,72. It would have been obvious to one of ordinary skill in the art to utilize SIS as taught by Sybert et al. for the natural tissue in Gabbay's spinal implant because of the abundance of SIS and its durability. Additionally it would have been obvious to one of ordinary skill in the art to use braided constructions as taught by Sybert et al. for the implant of Gabbay such that it increases the strength of the prosthesis to better stabilize the spine.

Claims 17,18,27,45-47,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhanna (6936070) in view of Lambrecht et al. (2002/151979).

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Muhanna discloses (Fig. 4B) an implant **16** having a length introduced into the disc **21** space. It can be seen that the implanted or second folded configuration has a multiplicity of pleated folds. Muhanna also discloses natural tissue, such as pericardium can be used for the material, col. 4, lines 38,50-54. Fig. 3A illustrates the tissue can include a drawstring **15**. However, Muhanna fails to disclose the drawstring passes through the tissue at a multiplicity of sites along the length of the tissue. Lambrecht et al. teach (Fig. 49G) that the drawstring **406** passes through the implant or tissue at a multiplicity of sites. Lambrecht also teaches the filament aids in manipulating the implant or tissue in the site of implantation, paragraph 213. As best understood, it would have been obvious to one of ordinary skill in the art to use a multiplicity of sites to secure the drawstring as taught by Lambrecht et al. with the tissue implant inserted in the disc by the method of Muhanna such that it is properly spaced in the disc space entirely to fill the area. Since the site accessed in the patient is minimal or small, the Examiner considers the tissue site or vertebral disc and annulus to aid in holding the tissue essentially in place as the implant is inserted and once it begins to fill the area it causes folding. With respect to claims 45,46, Lambrecht discloses (paragraph 207) the drawstring passes through a multiplicity of sites of the implant of at least 5, see Figs. 49G,50F. Regarding claim 47, Lambrecht fails to explicitly disclose at least ten sites of passing the drawstring through the implant. It would have been an obvious expedient to one of ordinary skill in the art to pass the drawstring through at least 10 sites on the implant since such a modification only involves routine skill in the art and provides predictable results in strengthening the tissue and the ability to manipulate it. Regarding

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claim 49, Muhanna fails to disclose the tissue is braided. Lambrecht et al. teach (paragraph 209) that the tissue material can be woven (braided). It would have been obvious to one of ordinary skill in the art to use a braided tissue as taught by Lambrecht with the method of Muhanna such that it reinforces or gives a stronger implant material. With respect to claim 50, Muhanna fails to disclose a cannula to deliver the tissue to the disc space. Lambrecht et al. teach the use of a cannula to deliver a tissue implant to the disc space, paragraphs 208,210,211. It would have been obvious to one of ordinary skill in the art to use a cannula as taught by Lambrecht et al. with the method of Muhanna to deliver the implant in the disc space and not have it possibly be placed outside the area inadvertently.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muhanna '070 in view of Lambrecht et al. (2002/151979) as applied to claim 27 above, and further in view of Sybert et al. (2002/107570). Muhanna as modified by Lambrecht et al. is explained supra. However, Muhanna in view of Lambrecht fail to teach small intestine submucosa for the tissue implant. Sybert et al. is also explained above. It would have been obvious to one of ordinary skill in the art to use SIS as taught by Sybert et al. with the method of repairing a disc disclosed by Muhanna modified in view of Lambrecht et al. such that it gives the ability to use a versatile tissue that can be easily obtained.

Response to Arguments

Applicant's arguments with respect to claim 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738